CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

83-900

CORRESPONDENCE

ORIG

SK&F

SMITH KLINE & FRENCH LABORATORIES
1500 Spring Garden Street, P.O. Box 7929, Philadelphia, Pennsylvania 19101 • 215-854-4000
cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

RESUBMISSION

NDA ORIG AMENDMENT.

FPL

February 19, 1976

NDA 83-900
'Benzedrine' Tablets

Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs HFD #530
Attention: Document Control Room 16-72
Department of Health, Education and Welfare
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Gentlemen:

In response to Dr. Seife's communication dated October 29, 1975 in reference to our NDA 83-900 for 'Benzedrine' (amphetamine sulfate) Tablets, information is provided herewith to satisfy the following:

a) Adequate information concerning the methods used in the synthesis, extraction, isolation or purification of the amphetamine base and its final conversion to the sulfate

A Drug Master File describing the methods, facilities and controls used for our production of Amphetamine Sulfate has been submitted to the FDA. We will notify your Division upon receipt of notice of assignment of a Master File Number to that information.

b) Include a fully completed set of production work records and related quality control reports from an actual production size run of this product

Attachment A contains copies of production records and analytical laboratory data for a typical production batch of 'Benzedrine' Tablets.

c) The printed package insert and all container labels in use with this product

Attachment B contains twelve (12) copies of the Prescribing Information and Immediate Container Labels currently used for the two dosage strengths of this product.

In addition, to make them current, the revisions indicated below have been made in the Controls Sections of our New Drug Application as originally submitted August 6, 1971 and as updated July 5, 1972, April 6, 1973 and October 15, 1975.

Section 6 - Page 1 Section 8 - Page 5	Updated to reflect the use of rather than Water
Section 8 - Page 6, 6a	Updated to reflect the current use of bottles for packaging
Section 8 - Page 10	Updated to reflect the use of a 5 year expiration date.

Sincerely,

J. F. Cassin

J. F. Cassin
Manager, Regulatory Affairs

Att.
kb

NDA 83-900

AF 14-395

OCT 29 1975

Smith Kline & French Laboratories
Attention: J. F. Cassin
1500 Spring Garden Street
Philadelphia, PA 19101

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Benzedrine (Amphetamine Sulfate) Tablets, 5 mg. and 10 mg.

Reference is also made to your communications dated February 22, September 17, October 15, 1973, July 26, December 10, 1974, and October 15, 1975.

The application is inadequate under section 505(b)(4) of the Act in that it fails to contain the following information required in an application:

Adequate information concerning the methods used in the synthesis, extraction, isolation or purification of the amphetamine base and its final conversion to the sulfate.

Adequate information concerning the methods used in, and the facilities and controls used for the manufacturing, processing, packing and holding of the drug dosage form. In this regard include a fully completed set of production work records and related quality control reports from an actual production size run of this product.

Submit the printed package insert and all container labels in use with this product.

Please let us have your response promptly.

cc:

Sincerely yours,

Marvin Seife 10/29/75

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

10/29/75

NDA ORIG AMENDMENT

Robert L. Dean, Vice President, Regulatory and Government Affairs-U.S. 215-854-5194

FPL

SMITH KLINE & FRENCH LABORATORIES

1500 Spring Garden Street, Philadelphia, Pennsylvania 19101

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

December 10, 1974

NDA ~~17-071~~
~~17-072~~ 13-700

Special new-drug application
supplement--changes being effected

Office of Scientific Evaluation
Bureau of Drugs
Department of Health, Education and Welfare
Food and Drug Administration
Parklawn Building, 5600 Fishers Lane
Rockville, Maryland 20852

Gentlemen:

In accordance with 314.8(d) and (e), I am enclosing 12 final printed copies each of the immediate container labels for 'Benzedrine' (brand of amphetamine sulfate) Spansule Capsules, 15 mg. (50s, placed in use in August, 1974), 5 mg. Tablets (100s, placed in use in September, 1974) and 10 mg. Tablets (100s, placed in use in October, 1974), revised to change "from this bulk package" to "this product" in the safety closure statement.

Sincerely yours,

Robert L. Dean

RLD/awd

Enclosures

SmithKline

NDA ORIG AMENDMENT

Robert L. Dean, Vice President, Regulatory and Government Affairs-U.S. 215-854-5194

SMITH KLINE & FRENCH LABORATORIES

1500 Spring Garden Street, Philadelphia, Pennsylvania 19101

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

FPLP

July 26, 1974

NDA 17-071
~~17-072~~ 83-900

Barrett Scoville, M.D., Director
Division of Neuropharmacological Drug Products
Office of Scientific Evaluation
Bureau of Drugs, DHEW
Food and Drug Administration
Parklawn Building - 5600 Fishers Lane
Rockville, Maryland 20852

Dear Doctor Scoville:

In accordance with the requests in your letter of April 30, 1974, I am submitting twelve final printed copies of prescribing information for 'Benzedrine' (brand of amphetamine sulfate) Spansule Capsules and Tablets revised to conform with the January 29, 1973 draft guideline labeling for single-entity amphetamine products (BZ:L17).

As requested, this labeling also includes, under ACTIONS, FDA's suggested statement regarding 'Benzedrine' Spansule capsules, and the following additional information:

1) Under "WARNINGS - Usage in Children," we have stated that amphetamines are not recommended in minimal brain dysfunction in children under three years of age.

2) Under "DOSAGE AND ADMINISTRATION - Narcolepsy," we have included specific dosage recommendations for pediatric and adult patients and suggested dosage increments and times of administration.

3) Under "DOSAGE AND ADMINISTRATION - Minimal Brain Dysfunction in Children," we have retained from our current labeling the paragraph stating that once symptoms have been controlled it may be possible to reduce dosage or interrupt therapy during summer months, since this information is useful to physicians. We have also included recommendations on the times of administration of tablet and 'Spansule' capsule dosage forms.

4) Similarly, under "DOSAGE AND ADMINISTRATION - Exogenous Obesity," we have adapted the guideline dosage recommendations to the use of 'Spansule' capsules, included suggested times of administration, and repeated the warning that 'Benzedrine' is not recommended for the treatment of obesity in children under 12 years of age.

RECEIVED
JUL 30 1974

WITHDRAWN

SmithKline

NDA 17-071

5) Under "OVERDOSAGE - Treatment," we have retained from our current labeling the paragraph dealing with overdosage of 'Spansule' capsules.

This labeling will be put into use next month.

In addition, as requested in your letter, I am enclosing twelve copies of the immediate container label for 15 mg. 'Benzedrine' Spansule capsules (50's). This label was placed in use in August, 1973, and submitted to FDA on October 15, 1973.

We noticed in the Federal Register of June 19, 1974, that the notice, "Drugs for Human Use — Drug Efficacy Study Implementation Certain Single Entity Oral Anoretic Drugs in Conventional or Controlled Release Dosage Forms" (39:26459), does not appear to require an initial box warning in the package insert, whereas the Guideline Labeling for Single-Entity Amphetamine Products, which we have followed in revising 'Benzedrine' labeling, does require a box warning. Is this box warning something we might omit in the next printing?

Sincerely yours,

Robert L. Dean

RLD:jh

Enclosures

NDA ORIG AMENDMENT SK&F

FPLI

ORIG

Robert L. Dean, Vice President, Regulatory and Government Affairs-U.S.

SMITH KLINE & FRENCH LABORATORIES

1500 Spring Garden Street, Philadelphia, Pa. 19101 • 215 LOcust 4-2400

October 15, 1973

NDA 17-071
~~17-072~~ (83-900)

"Special new drug application
supplement--changes being effected"

Office of Scientific Evaluation
Bureau of Drugs
Department of Health, Education and Welfare
Food and Drug Administration
5600 Fishers Lane, Parklawn Building
Rockville, Maryland 20852

Gentlemen:

In accordance with 130.9 (d) and (e), I am enclosing for your files 12 final printed copies each of the labels and labeling for 'Benzedrine' (brand of amphetamine sulfate):

1) revised prescribing information (BZ:L16) and immediate container label for 10 mg. Tablets (100s) to include the new corporate name, "Division of SmithKline Corporation," placed in use in September, 1973.

2) revised immediate container label for 15 mg. 'Spansule' Capsules (50s) to include the new corporate name and a change in the storage statement from "Keep in a cool, dry place" to "Store at controlled room temperature" to conform to standard compendial terminology. This was placed in use in August, 1973.

As stated in our letter of August 6, 1971, these submissions are made without prejudice to our position that 'Benzedrine' Spansule Capsules and Tablets are not "new drugs" as that term is defined in Section 201(p) of the Federal Food, Drug and Cosmetic Act and is covered by the grandfather clause enacted in Section 107 (c)(4) of the Drug Amendments of 1962.

Sincerely yours,

Robert L. Dean

RLD/awd

Enclosures

Division of
SmithKline
CORPORATION

NDA ORIG AMENDMENT

SK&F

Robert L. Dean, Vice President, Regulatory and Government Affairs-U.S.

FPLI

SMITH KLINE & FRENCH LABORATORIES
1500 Spring Garden Street, Philadelphia, Pa. 19101 • 215 LOcust 4-2400

September 17, 1973

ANDA 83-900
~~NDA 17-072~~

"Special new-drug application
supplement--changes being effected"

Office of Scientific Evaluation
Bureau of Drugs
Department of Health, Education and Welfare
Food and Drug Administration
Parklawn Building, 5600 Fishers Lane
Rockville, Maryland 20852

Gentlemen:

In accordance with 130.9 (d) and (e), I am enclosing for your files 12 final printed copies of a slightly revised immediate container label, placed in use in July, 1973, for 'Benzedrine' (brand of amphetamine sulfate) Tablets, 5 mg. (100s). The only change is the addition of the new corporate name -- Division of SmithKline Corporation.

As stated in our letter of August 6, 1971, these submissions are made without prejudice to our position that 'Benzedrine' Spansule Capsules and Tablets are now "new drugs" as that term is defined in Section 201(p) of the Federal Food, Drug and Cosmetic Act and is covered by the grandfather clause enacted in Section 107(c)(4) of the Drug Amendments of 1962.

Sincerely yours,

Robert L. Dean

RECEIVED
SEP 26 1973
BUREAU OF DRUGS

RLD/awd

Enclosures

Acting Director
Office of Scientific Evaluation

June 18, 1973

Thru: Director
Division of Actions Implementation, DESI

Acting Director
Division of Neuropharmacological Drug Products

Proposal to Transfer Single Entity Amphetamine and Dextroamphitamine NDAs to DESI: ACTION MEMORANDUM

FACTS

We are recommending the transferring of some 27 single entity amphetamine and dextroamphetamine NDAs (List attached) to the Division of Actions Implementation, DESI, since the 2/12/73 Federal Register Announcement (attached) now requires ANDAs for these products. All of these NDAs have been resubmitted since 2/12/73.

It would appear that for consistency of policy DESI should handle all of these products together. DESI now has pending 10-12 of these type products submitted since, 2/12/73, some of which have been submitted by firms that also have different dosage forms now pending in DNDP.

We have talked with Jack Meyer and he is agreeable to such a transfer. The applicants would have to be notified and a new ANDA number assigned to each.

Barrett Scoville, M.D.

Concur_____ Nonconcur_____ Date_____

Prepared By: BD-120, BYERS , 6/18/73,X33810

cc:
BD-100 BD-120 BD-69/Dr.Selfe FT/cld/6/18/73/BD-120/~~Dr.Gocklin~~ B.BYER
BD-100/Dr.Leong CA-228
BD-120/Dr.Scoville

NDA ORIG AMENDMENT

SK&F

FPU

Robert L. Dean, Vice President, Regulatory and Government Affairs - U.S. Pharmaceuticals

SMITH KLINE & FRENCH LABORATORIES
1500 Spring Garden Street, Philadelphia, Pa. 19101 • 215 LOcust 4-2400

ORIG

NDA 17-071
17-072

February 22, 1973

"Special new-drug application
supplement--changes being effected"

Office of Scientific Evaluation
Bureau of Drugs
Food and Drug Administration
Department of Health, Education and Welfare
Parklawn Building - 5600 Fishers Lane
Rockville, Maryland 20852

Gentlemen:

In accordance with 130.9 (d) and (e) and with the Federal Register notice of April 27, 1972, for "Child Protection Packaging Standards for Preparations Subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970," I am enclosing for your files 12 final printed copies each of slightly revised immediate container labels for 'Benzedrine' (brand of amphetamine sulfate) Spansule Capsules, 15 mg. (50s) and Tablets, 5 mg. and 10 mg. (100s). The only change is the addition of the following safety closure statement:

> "Important: Use safety closures when dispensing from this bulk package unless otherwise directed by physician or requested by purchaser."

This labeling was placed in use 1) for 'Spansules' in January, 1973, and 2) for Tablets in February, 1973.

As stated in our letter of August 6, 1971, these submissions are made without prejudice to our position that 'Benzedrine' Spansule Capsules and Tablets are not "new drugs" as that term is defined in Section 201(p) of the Federal Food, Drug and Cosmetic Act and is covered by the grandfather clause enacted in Section 107 (c)(4) of the Drug Amendments of 1962.

Sincerely yours,

Robert L. Dean

RLD:db

Enclosures

2

Rev. W/F

SK&F
JJH
ORIG

Robert L. Dean, Vice President, Regulatory and Government Affairs - U.S. Pharmaceuticals

SMITH KLINE & FRENCH LABORATORIES

1500 Spring Garden Street, Philadelphia, Pa. 19101 • 215 LOcust 4-2400

April 6, 1973

RESUBMISSION

NDA 17-072

NDA ORIG AMENDMENT

Elmer A. Gardner, M.D., Director
Division of Neuropharmacological Drug Surveillance
Office of Scientific Evaluation
Bureau of Drugs
Department of Health, Education and Welfare
Food and Drug Administration
Parklawn Building - 5600 Fishers Lane
Rockville, Maryland 20852

Dear Doctor Gardner:

In response to your letter of February 9, 1973, requesting revised labeling and additional information on 'Benzedrine' (brand of amphetamine sulfate) Tablets, we are submitting the following:

Enclosure 1: Draft labeling for 'Benzedrine' Spansule Capsules and Tablets that conforms with the guideline labeling for single-entity amphetamine products.

The DOSAGE AND ADMINISTRATION section has been expanded slightly to include information (e.g., on initial therapy, dose titration, discontinuation of medication) that would be useful to physicians or to make this section relevant for 'Spansule' capsules. Similarly, under OVERDOSAGE-TREATMENT, we have added information pertinent for 'Spansule' capsules and also the following sentence after the statement on phentolamine: "However, a gradual drop in blood pressure will usually result when sufficient sedation has been achieved."

Enclosure 2: Memo from A. E. DeWald providing the following information: specification of the used in the final dosage form; clarification of the averaging of three ultraviolet scans in the final dosage form assay; a commitment to continue stability studies on the final dosage form packaged in bottles.

As stated in our letter of August 6, 1971, this submission is made without prejudice to our position that 'Benzedrine' Tablets is not a "new drug" as that term is defined in Section 201(p) of the Federal Food, Drug and Cosmetic Act and is covered by the grandfather clause enacted in Section 107 (c)(4) of the Drug Amendments of 1962.

Sincerely yours,

Robert L. Dean

APR 11 1973

BUREAU OF DRUGS

RLD:jh

Enclosures

(2)

FEB 9 1973

NDA 17-072

AF 14-395

Smith, Kline and French Laboratories
Attention: Robert L. Dean
1500 Spring Garden Street
Philadelphia, Pennsylvania 19104

Gentlemen:

Reference is made to your new drug application dated August 6, 1971 submitted pursuant to section 505(b) of the Federal Food, Drug , and Cosmetic Act for the preparation Benzedrine (amphetamine sulfate) Tablets.

We also acknowledge receipt of your additional communications dated November 15, 1971, April 6, 1972, May 5, 1972, July 7, 1972 and October 11, 1972.

We have completed our review of this application. However, before we are able to reach a conclusion the following additional information is necessary:

Revised labeling to conform to the enclosed draft copy.

Specify the talc used in the final dosage form. The designation "Canadian 'AA-1' or equivalent" is too general. In addition, it is recommended that the be tested for presence of asbestos either by you or your supplier.

Clarify the averaging of three ultraviolet scans in the final dosage form assay.

A commitment to continue the stability studies on the final dosage form packaged in bottles.

Please submit the above information within 60 days of the date of this letter.

Sincerely yours,

cc:

Elmer A. Gardner, M.D.
Director
Division of Neuropharmacological
Drug Products
Office of Scientific Evaluation
Bureau of Drugs

Orig grade

SK&F

Robert L. Dean, Vice President, Regulatory and Government Affairs - U.S. Pharmaceuticals NDA ORIG AMENDMENT

SMITH KLINE & FRENCH LABORATORIES FPL

1500 Spring Garden Street, Philadelphia, Pa. 19101 • 215 LOcust 4-2400

October 11, 1972

NDA 17-071
17-072

"Special new-drug application
supplement—changes being effected"

Office of Scientific Evaluation
Bureau of Drugs
Department of Health, Education and Welfare
Food and Drug Administration
Parklawn Building, 5600 Fishers Lane
Rockville, Maryland 20852

Gentlemen:

In accordance with 130.9 (d) and (e), I am enclosing for your files 12 final printed copies of a slightly revised prescribing information for 'Benzedrine' (brand of amphetamine sulfate) Spansule Capsules and Tablets. On page 2, paragraph 2 under WARNINGS has been revised to clarify the section concerning the operation of vehicles or machinery.

I am also enclosing 12 final printed copies of a slightly revised immediate container label for 'Benzedrine' Spansule Capsules, 15 mg. (50s). The 'Spansule' description has been changed to "...so prepared that an initial dose is released promptly and the remaining medication is released gradually over a prolonged period" to conform to the prescribing information submitted to FDA 5/5/72.

The above labeling was placed in use in August, 1972.

As stated in our letter of August 6, 1971, these submissions are made without prejudice to our position that the 'Benzedrine' Tablets and Spansule Capsules are not "new drugs" as that term is defined in Section 201(p) of the Federal Food, Drug and Cosmetic Act and is covered by the grandfather clause enacted in Section 107(c)(4) of the Drug Amendments of 1962.

Sincerely yours,

OCT 16 1972

BUREAU OF DRUGS

RLD:db

Enclosures

ENCLOSURES IN CHECKOUT ONLY

17-071

BOTH JACKETS

NDA ORIG AMENDMENT

SK&F

rt L. Dean, Vice President, Regulatory and Government Affairs - U.S. Pharmaceuticals

Orig

SMITH KLINE & FRENCH LABORATORIES
1500 Spring Garden Street, Philadelphia, Pa. 19101 • 215 LOcust 4-2400

July 7, 1972

NDA 17-072

Office of Scientific Evaluation
Bureau of Drugs
Food and Drug Administration
Department of Health, Education and Welfare
Parklawn Building, 5600 Fishers Lane
Rockville, Md. 20852

Gentlemen:

Attached hereto are minor modifications which have been made in the facilities and controls sections of the information submitted on 'Benzedrine' Tablets dated August 6, 1971 to amend that information so as to make it current.

As stated in our letter of August 6, 1971, this submission is made without prejudice to our position that 'Benzedrine' Tablets is not a "new drug" as that term is defined in Section 201(p) of the Federal Food, Drug & Cosmetic Act and is covered by the grandfather clause enacted in Section 107(c)(4) of the Drug Amendments of 1962.

Sincerely yours,

Robert L. Dean

RECEIVED
JUL 13 1972
BUREAU OF DRUGS

Att.
kb

(2)

NDA ORIG AMENDMENT

SK&F

Robert L. Dean, Vice President, Regulatory and Government Affairs - U.S. Pharmaceuticals

SMITH KLINE & FRENCH LABORATORIES

1500 Spring Garden Street, Philadelphia, Pa. 19101 • 215 LOcust 4-2400

FPL

May 5, 1972

Orig

NDA 17-071
17-072

"Special new drug application
supplement--changes being effected"

Office of Scientific Evaluation
Bureau of Drugs
Department of Health, Education and Welfare
Food and Drug Administration
Parklawn Building, 5600 Fishers Lane
Rockville, Maryland 20852

Gentlemen:

In accordance with 130.9 (d) and (e), I am enclosing for your files twelve (12) final printed copies of a slightly revised prescribing information for 'Benzedrine' (brand of amphetamine sulfate) Spansule Capsules and Tablets. The only change is in the 'Spansule' DESCRIPTION on page 1: the phrase beginning "...so prepared that a therapeutic dose..." has been changed to "...so prepared that an initial dose is released promptly and the remaining medication is released gradually over a prolonged period" in order to improve product description. This labeling was placed in use in March, 1972.

As stated in our letter of August 6, 1971, these submissions are made without prejudice to our position that the 'Benzedrine' Tablet and Spansule Capsules are not "new drugs" as that term is defined in Section 201(p) of the Federal Food, Drug and Cosmetic Act and is covered by the grandfather clause enacted in Section 107(c)(4) of the Drug Amendments of 1962.

Sincerely yours,

Robert L. Dean

RECEIVED
MAY 10 1972
BUREAU OF DRUGS

RLD/awd

Enclosures: BZ:L14

(2)

NDA ORIG AMENDMENT SK&F

Robert L. Dean, Vice President, Regulatory and Government Affairs - U.S. Pharmaceuticals

SMITH KLINE & FRENCH LABORATORIES

1500 Spring Garden Street, Philadelphia, Pa. 19101 • 215 LOcust 4-2400

Orig

April 6, 1972

NDA 17-072

Office of Scientific Evaluation
Bureau of Drugs
Food and Drug Administration
Department of Health, Education, and Welfare
Parklawn Building, 5600 Fishers Lane
Rockville, Md. 20852

Gentlemen:

As I promised in my letter of November 15, 1971, I am enclosing for your files twelve (12) final printed copies of the immediate container label for 'Benzedrine' (brand of amphetamine sulfate) Tablets, 10 mg. (100s). This labeling was placed in use in March, 1972.

As stated in our letter of August 6, 1971, these submissions are made without prejudice to our position that the 'Benzedrine' Tablet and Spansule Capsule are not "new drugs" as that term is defined in Section 201(p) of the Federal Food, Drug & Cosmetic Act and is covered by the grandfather clause enacted in Section 107(c)(4) of the Drug Amendments of 1962.

Sincerely yours,

Robert L. Dean

RLD:clr

Enclosures

RECEIVED
APR 12 1972
BUREAU OF DRUGS

(2)

NDA ORIG AMENDMENT DS &F

rt L. Dean, Vice President, Regulatory and Government Affairs - U.S. Pharmaceuticals

WITH KLINE & FRENCH LABORATORIES

ORIG

Spring Garden Street, Philadelphia, Pa. 19101 • 215 LOcust 4-2400

November 15, 1971

Elmer A. Gardner, M.D., Director
Division of Neuropharmacologic Drug Surveillance
Office of Marketed Drugs
Bureau of Drugs
Department of Health, Education & Welfare
Food and Drug Administration
Parklawn Building - 5600 Fisher's Lane
Rockville, Maryland 20852

NDA 17-072

NDA 17 672

Dear Doctor Gardner:

On August 6, 1971, we submitted New Drug Applications for 'Benzedrine' Tablet and Spansule Capsules in response to the Federal Register Notice 35:12652 of August 8, 1970. At that time, we submitted xeroxed copies of the package insert (prescribing information) and the immediate container labels for the 5 mg. Tablet (100's), the 10 mg. Tablet (100's) and the 15 mg. Spansule Capsule (50's). For your files, I am now submitting 12 final printed copies of the prescribing information and the immediate container labels for the 5 mg. Tablet and 15 mg. Spansule Capsule. This labeling will be placed in use by December 1, 1971. Labels for the 10 mg. Tablet, which have not been printed yet, will be sent to you when available.

As stated in our letter of August 6, these submissions are made without prejudice to our position that the 'Benzedrine' Tablet and Spansule Capsule are not "new drugs" as that term is defined in Section 201 (p) of the Federal Food, Drug and Cosmetic Act and is covered by the grandfather clause enacted in Section 107(c)(4) of the Drug Amendments of 1962.

Sincerely yours,

Robert L. Dean

RLD/awd

enclosures

BOTH JACKETS

Our Reference
NDA 17-072
AF 14-935

FEB 3 1972

Smith Kline and French Laboratories
Attention: Robert L. Dean
1500 Spring Garden Street
Philadelphia, Pennsylvania 19101

Gentlemen:

We acknowledge receipt of your new drug application submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug: Benzedrine Tablets

Date of Application: August 6, 1971

Date of Receipt: August 9, 1971

In view of the large number of applications submitted for various formulations of amphetamines and related products, and in view of the unusual public health problems involved, we have found it necessary to develop special criteria and procedures for the review and evaluation of the safety and efficacy of anorectic agents, including amphetamines, prior to taking any action on individual new drug applications.

Because of the magnitude of this review and evaluation and in accordance with section 505(c) of the Federal Food, Drug and Cosmetic Act, we request an extension of time to August 3, 1972 for the completion of our review of your application.

We regret the delay in acknowledging the receipt of your submission. We will correspond with you further after we have had the opportunity to complete our review and evaluation.

Please identify any communications concerning this application with the NDA number shown above.

cc:

Sincerely yours,

Elmer A. Gardner, M.D.
Director
Division of Neuropharmacological
Drug Products
Office of Scientific Evaluation
Bureau of Drugs

Robert L. Dean, Vice President, Regulatory and Government Affairs - U.S. Pharmaceuticals NEW DRUG APPLICATION 17-072

SK&F

SMITH KLINE & FRENCH LABORATORIES

1500 Spring Garden Street, Philadelphia, Pa. 19101 • 215 LOcust 4-2400

August 6, 1971

Elmer A. Gardner, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Scientific Evaluation, Bureau of Drugs
Department of Health, Education and Welfare
Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20852

Dear Doctor Gardner:

This 'Benzedrine' Tablet NDA has been prepared in response to the Federal Register Notice 35:12652 of August 8, 1970, which calls for new drug applications to be submitted for amphetamine drugs within one year.

We continue to believe that the 'Benzedrine' tablet is not a "new drug" as that term is defined in Section 201(p) of the Federal Food, Drug & Cosmetic Act and, moreover, is covered by the grandfather clause enacted in Section 107(c)(4) of the Drug Amendments of 1962. This submission is made without prejudice to that position. Specifically, we do not concede the validity of the August 8, 1970 notice as it purports to apply to this product, and we reserve the right to urge in any appropriate proceeding that an approved NDA is not required for the product's continued marketing.

Since 'Benzedrine' (d,l amphetamine sulfate) was marketed in 1936, physicians have found it to be safe and effective in the treatment of narcolepsy, minimal brain dysfunction in children, and as an adjunct in weight reduction therapy. In the past several decades, hundreds of reports of animal studies, controlled and uncontrolled clinical studies have appeared in the published literature, and 'Benzedrine', being the first available amphetamine, became the standard against which other amphetamines and stimulants were compared.

Because 'Benzedrine' has been available for so many years, this NDA is not the usual summary of new data from an organized investigational program, but rather, it is a summary of animal studies conducted by SK&F and by others, and of the controlled and uncontrolled clinical studies published during the years of clinical use. For clarity, we have prepared three separate sections (E1 through E8), one for each of the indications: narcolepsy, minimal brain dysfunction in children; and as an adjunct in weight reduction therapy. Bioavailability studies have been included which compare the blood levels and urinary excretion obtained with both dosage forms of 'Benzedrine' (Tablets and 'Spansule' Sustained Release Capsules).

Sincerely yours,

Robert L Dean

Robert L. Dean

RLD/ams

NDA 83-900/S-001

APR 5 1976

Smith Kline & French Laboratories
Attention: J.F. Cassin
1500 Spring Garden Street
P.O. Box 7929
Philadelphia, PA 19101

Gentlemen:

We acknowledge receipt on March 31, 1976, of your communication of March 31, 1976. This is regarded as a supplemental new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Benzedrine (Amphetamine Sulfate) Tablets, 5 mg. and 10 mg.

The supplemental application provides for manufacturing revisions.

We have completed the review of this supplemental application and it is approved. Our letter of February 26, 1976, detailed the conditions relating to the approval of this application.

The material submitted is being retained in our file.

Sincerely yours,

R. Sanzbar 4/15/76

for Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

14/76
6
4/14/76

SMITH KLINE & FRENCH LABORATORIES
1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101 • 215-854-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

March 31, 1976

NDA 83-900
'Benzedrine'
Tablets

NDA NO. 83900 REF. NO. 51001
Manufacturer: Smith Kline Chem.

Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs HFD #530
Document Control Room #16-72
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Gentlemen:

In accordance with the commitment in our amendment dated February 19, 1976 to our New Drug Application #83-900 for 'Benzedrine' (amphetamine sulfate) Tablets, Page 1 of Section 8 of our Methods, Facilities and Controls used for the product has been revised to reflect that the designation DMF has been assigned to our Drug Master File describing the methods, facilities and controls used for the production of the drug substance Amphetamine Sulfate (copy attached).

Sincerely,

J.F. Cassin

J. F. Cassin
Manager, Regulatory Affairs

Att.
kb

NDA 83-900/S-002

Smith Kline & French Laboratories
Attention: J.F. Cassin
1500 Spring Garden Street
P.O. Box 7929
Philadelphia, PA 19101

Gentlemen:

We acknowledge receipt on April 12, 1977, of your communication of April 12, 1977. This is regarded as a supplemental new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amphetamine Sulfate Tablets, 5 mg.

The supplemental application provides for revised container labels.

We have completed the review of this supplemental application and it is approved. Our letter of February 26, 1976, detailed the conditions relating to the approval of this application.

The material submitted is being retained in our files.

Sincerely yours,

Marvin Seife 5/11/77

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc:

5/11/77

5/10/77

SK&F

ORIG

SMITH KLINE &FRENCH LABORATORIES

1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101 • 215-854-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

NDA 83-900
'Benzedrine' Tablets

April 12, 1977

Division of Generic Drug Products
Office of Drug Monographs
Bureau of Drugs HFD #530
Attn: Document Control Room 16-72
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 83-900 PT ... S/006
NDA SUPPL FOR Labeling Revision

FPL

Gentlemen:

In accordance with § 314.8 (a)(5)(ix), I am enclosing 12 final printed copies of immediate container labels for 'Benzedrine' (brand of amphetamine-sulfate) Tablets, 5 mg. (100's - Code AG) revised to add the word "Expires". No expiration date has been used previously for the 5 mg. strength of this product. This label will be placed in use in May.

Code AG also differs from prior labeling in that the NDC number has been changed from alpha-numeric to all numeric to facilitate adaptation into computerized drug programs.

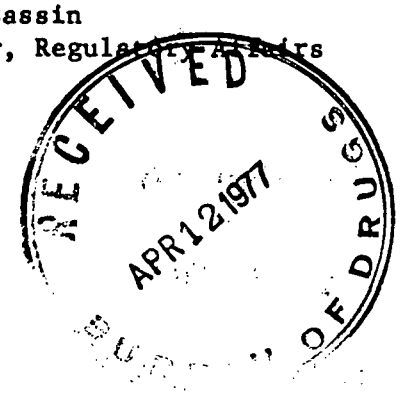
Similar label changes were submitted for the 10 mg. strength product October 15, 1975.

Stability data was incorporated in the Facilities and Controls Section 8, pages 11 and 12, of our original submission dated August 6, 1971 and later updated in our communication dated October 15, 1975 to substantiate a 5 year expiration date for both strengths of this product.

Sincerely,

J. F. Cassin

J. F. Cassin
Manager, Regulatory Affairs



att.
jm

NDA 83-900/S-005

Smith Kline & French Laboratories
Attention: J.F. Cassin
1500 Spring Garden Street
P.O. Box 7929
Philadelphia, PA 19101

Gentlemen:

Reference is made to your supplement dated December 20, 1978 regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Benzedrine (Amphetamine Sulfate) Tablets, 5 mg. and 10 mg.

The supplemental application provides for revised package insert (BZ:L19) dated November 1978.

We have completed the review of this supplemental application and it is approved. Our letter of February 26, 1976 detailed the conditions relating to the approval of this application.

The material submitted is being retained in our files.

Sincerely yours,

Marvin Seife 2/11/81

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

#7.13
2/10/81

SK&F
a SmithKline company

SMITH KLINE & FRENCH LABORATORIES
1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101 • 215-854-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

December 20, 1978

NDA 83-900
'Benzedrine' Tablets

Docket No. 78N-0278

Special new drug application
Supplement - changes being effected

NDA NO. 83-900 REF. NO. 1085
NDA SUPPL FOR Labeling Rev
FPL

Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs, HFD #530
Document Control Room #16-72
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Gentlemen:

In accordance with 314.8 (d)(e), I have enclosed 12 final printed copies of the package insert (BZ:L19) for 'Benzedrine' (brand of amphetamine sulfate) revised to conform to the Federal Register of October 24, 1978 ("Uniform Physician Labeling for Stimulant Drugs for Children"). The previous insert (BZ:L18) was never used in a production run.

This labeling will be placed in use early in February, 1979.

Sincerely yours,

M. J. McErlee for

J.F. Cassin
Manager, Regulatory Affairs

JFC/jh
Enclosures

SK&F
a SmithKline company

SMITH KLINE &FRENCH LABORATORIES
1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101 • 215-854-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

February 6, 1979

NDA 83-900

Special new drug application
Supplement - changes being effected

NDA NO. 83-900 REF. NO. 57006
NDA SUPPL FOR Label Rev

Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs, HFD #530
Document Control Room #16-72
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

FPL

Gentlemen:

In accordance with 314.8 (d)(e), I have enclosed 12 final printed copies of the immediate container label for 'Benzedrine' (brand of amphetamine sulfate) Tablets, 10 mg. (100's) revised:

a) to add the word "Tablets" to the product name;
b) to reposition the NDC number on the right-hand side of this single-panel label;
c) under USUAL DOSAGE, to change "prescribing data" to "prescribing information".

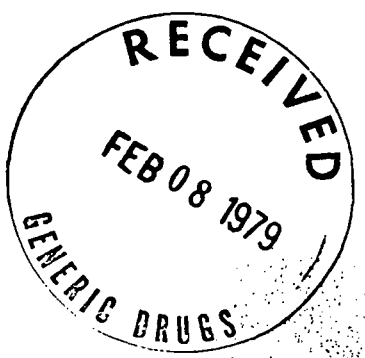
This labeling is scheduled to be placed in use in March, 1979.

Sincerely yours,

J. F. Cassin

J.F. Cassin
Manager, Regulatory Affairs

JFC/slh
Enclosures



MAY 11 1982

NDA 83-900/S-007

Smith, Kline and French Laboratories
Attention: J.F. Cassin
1500 Spring Garden Street
P.O. Box 7929
Philadelphia, Pennsylvania 19101

Gentlemen:

Reference is made to your supplement dated September 14, 1979, regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Benzedrine (Amphetamine Sulfate) Tablets, 5 mg. and 10 mg.

Also referenced is your letter of February 11, 1982.

The supplemental application provides for updated component, composition, and methods/facilities/controls information.

We have completed the review of this supplemental application and it is approved. Our letter of February 26, 1976 detailed the conditions relating to the approval of this application.

Please be advised that an extension of expiration date must be requested as a supplemental application with supporting data.

Also, although approved, the information in this supplement (S-007) should again be updated to reflect the new compendial references (USP XX/NF XV).

The material submitted is being retained in our files.

Sincerely yours,

Marvin Seife 5/11/82

cc: PHI-DO

Marvin Seife, M.D.
Director
/MSeife Division of Generic Drug Monographs
?(7729A) Office of Drug Monographs
Bureau of Drugs

on May 7, 1982
5/10/82

SK&F
a SmithKline company

SMITH KLINE &FRENCH LABORATORIES
1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101 • 215-854-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

September 14, 1979

NDA 83-900

Marvin Seife, M.D.
Director, Division of Generic Drug Monographs
Food and Drug Administration
HFD #530; Document Room #16-72
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 83 900 REF. NO. 5/SC7
NDA SUPPL FOR Control Rec

Dear Doctor Seife:

This supplement on 'Benzedrine' Tablets is submitted to provide updated information with respect to items 6 (components), 7 (composition) and 8 (methods, facilities and controls).

FPL

Submission of this supplement at this time should not be construed to waive or in any other manner affect our right to a hearing as provided for in the FR notice of July 17, 1979 (p. 41552-72) regarding the proposed removal of the indication for short-term adjunctive treatment in obesity from amphetamine products.

Sincerely yours,

J. F. Cassin

J.F. Cassin
Manager, Regulatory Affairs

JFC/slh

Enclosures

RECEIVED
SEP 17 1979
GENERIC DRUGS

SK&F
a SmithKline company

SMITH KLINE &FRENCH LABORATORIES
1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101 • 215-854-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

December 14, 1979

NDA 83-900

Special new drug application
Supplement - changes being effected

NDA NO. 12,900 REF. NO. S/002
NDA SUPPL FOR Label Rev

FDA, Bureau of Drugs
HFD #530 ; Document Control Room # 16-72
5600 Fishers Lane
Rockville, Maryland 20857

FPL

Gentlemen:

In accordance with 314.8 (d)(e) and in response to the Federal Register notice of August 25, 1978 ("Prescription Drug Dispensing Container Requirements"), I have enclosed 12 final printed copies of the immediate container label for:

'Benzedrine' (brand of amphetamine sulfate) Tablets, 5 mg. (100's)

revised to add

"Dispense in a tight, light-resistant container."

This labeling will be placed in use in January, 1980.

Sincerely yours,

J. F. Cassin

J.F. Cassin, C.E.P.
Manager, Regulatory Affairs

JFC/slh

Enclosures

SK&F
a SmithKline company

SMITH KLINE &FRENCH LABORATORIES
1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101 • 215-854-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

September 18, 1979

NDA 83-900/S-003, S-004
'Benzedrine' Tablets

SUPPL NEW CORRES

Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs HFD #530
Attn: Document Control Room 16-72
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Gentlemen:

In accordance with our prior commitment, submitted herewith is updated stability data for a representative batch of 'Benzedrine' Tablets reformulated as described in our supplemental application S-003, S-004 dated September 11, 1978 as approved November 21, 1978. Additional stability data will be submitted periodically as it becomes available.

Sincerely,

J. F. Cassin

J. F. Cassin
Manager, Regulatory Affairs

att.
jm

SK&F
a SmithKline company

SMITH KLINE &FRENCH LABORATORIES
1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101 • 215-854-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

August 11, 1980

NDA 83-900/S-003, S-004
'Benzedrine' Tablets

SUPPL NEW CORRES

Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs HFD #530
Attention: Document Control Room 16-72
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Gentlemen:

In accordance with our prior commitment, submitted herewith is updated stability data for a representative batch of 'Benzedrine' Tablets reformulated as described in our supplemental application S-003, S-004 dated September 11, 1978 as approved November 21, 1978. Additional stability data will be submitted periodically as it becomes available.

Sincerely,

J. F. Cassin

J. F. Cassin
Director, Regulatory Reports
and Advertising Review

kmcs

Attachment

RECEIVED
AUG 15 1980
GENERIC DRUGS

NDA 83-900/S-006, 008, & 009

FEB 11 1981

Smith Kline & French Laboratories
Attention: J.F. Cassin
1500 Spring Garden Street
P.O. Box 7929
Philadelphia, PA 19101

Gentlemen:

Reference is made to your supplement dated February 6, 1979 regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dentadrine (Amphetamine Sulfate) Tablets, 10 mg.

We also acknowledge receipt of your communications dated December 14, 1979 and February 29, 1980 which amended the supplement.

The supplemental application provides for revised container labels (100's) to include dispensing information.

We have completed the review of this supplemental application and it is approved. Our letter of February 26, 1976 detailed the conditions relating to the approval of this application.

The material submitted is being retained in our files.

Sincerely yours,

Marvin Seife 2/11/81

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

HFD
2/10/81

SK&F
a SmithKline company

SMITH KLINE &FRENCH LABORATORIES
1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101 • 215-854-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

February 29, 1980

NDA 83-900

Special new drug application
Supplement - changes being effected

NDA NO. 8390 REF. NO. 909
NDA SUPPL FOR. Label Rev

FDA, Bureau of Drugs
HFD #530; Document Control Room # 16-72
5600 Fishers Lane
Rockville, Maryland 20857

FPL

Gentlemen:

In accordance with 314.8 (d)(e) and in response to the Federal Register notice of August 25, 1978 ("Prescription Drug Dispensing Container Requirements"), I have enclosed 12 final printed copies of the immediate container label for:

'Benzedrine' (brand of amphetamine sulfate) Tablets, 10 mg.

revised to add "Dispense in a tight, light-resistant container."

This labeling will be placed in use in March, 1980.

Sincerely yours,

J. F. Cassin

J.F. Cassin
Manager, Regulatory Affairs

RECEIVED
MAR 07 1980
GENERIC DRUGS

JFC/slh

Enclosures

SK&F
a SmithKline company

SMITH KLINE & FRENCH LABORATORIES
1500 Spring Garden Street, P.O. Box 7929, Philadelphia, PA 19101 • (215) 751-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

February 11, 1982

NDA 83-900

SUPPL NEW CORRES

Marvin Seife, M.D.
Director, Division of Generic Drug Monographs
Food and Drug Administration
HFD #530; Document Room #16-72
5600 Fishers Lane
Rockville, Maryland 20857

ltr 5/18/82
Sup

Dear Doctor Seife:

On September 14, 1979 we submitted a supplemental application for 'Benzedrine' (amphetamine sulfate) Tablets to provide for updated information with respect to items 6 (components), 7 (composition) and 8 (methods, facilities and controls). To date no response has been received regarding this submission.

We would appreciate acknowledgement of receipt and/or any communication issued pertaining to this document. If you never received it, we wish to refile the document to complete our records.

Sincerely yours,

J. F. Cassin

J.F. Cassin
Director, Regulatory Editing
and Advertising Review

JFC/slh

RECEIVED
FEB 16 1982
GENERIC DRUGS

[redacted] 21 1978

NDA 83-900/S-003
S-004

Smith Kline & French Laboratories
Attention: J.F. Cassin
1500 Spring Garden Street
P.O. Box 7929
Philadelphia, PA 19101

Gentlemen:

Reference is made to your supplements dated September 11, 1978, regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amphetamine Sulfate Tablets, 5 mg. and 10 mg.

The supplemental applications provide for:

S-002 A revised formula

S-003 Manufacturing and control revisions attendant to the new formula.

We have completed the review of this supplemental application and it is approved. Our letter of February 26, 1976, detailed the conditions relating to the approval of this application.

The material submitted is being retained as part of your application.

Sincerely yours,

Marvin Seife 11/21/78

Marvin Seife, M.D.
Director
Division of Generic Drug Monggraphs
Office of Drug Monographs
Bureau of Drugs

cc:

Reviewed 1-20-78

78

SKGF

SMITH KLINE &FRENCH LABORATORIES
1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101 • 215-854-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

September 11, 1978

NDA 83-900
'Benzedrine' Tablets

NDA NO 8-900 REF. NO. -900-

NDA SUPPL FOR Formula Rev

S-024 manuf + Control Revision

Division of Generic Drug Products
Office of Drug Monographs
Bureau of Drugs HFD #530
Attn: Document Control Room 16-72
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Gentlemen:

Our New Drug Application for 'Benzedrine' (amphetamine sulfate) Tablets provides for the use of FD&C Red #2 as a coloring component of the product. As a result of the Federal Register notice dated February 10, 1976 (pages 5823-5825), which terminated the provisional listing of FD&C Red #2 for use in food, drugs and cosmetics the colorant composition was reformulated to use D&C Red and D&C Yellow in place of FD&C Red #2 and FD&C Yellow

This supplement is submitted in accordance with the provisions of §314.8(d)(3) and (e) to provide for this reformulation.

The change in colorant composition did not interfere with any assay or other control procedures used in manufacturing the drug product. Stability data obtained to date on a representative batch of the 10 mg. strength product is attached. Additional stability data will be submitted as it becomes available. Appropriate action will be taken on any marketed batches which may become subpotent.

Sincerely,

J. F. Cassin

J. F. Cassin
Manager, Regulatory Affairs

RECEIVED
SEP 11 1978
GENERIC DRUGS

att.
jm

OCT 11 1988

NDA 83-900

Smith Kline & French Laboratories
Attention: Raymond Ragland, Jr., Ph.D.
1500 Spring Garden Street, P.O. Box 7929
Philadelphia, PA 19101

Dear Sir:

We acknowledge the receipt of your communication dated August 24, 1988 requesting withdrawal of approval of your abbreviated new drug application for Benzedrine® (Amphetamine Sulfate) Tablets.

In compliance with your request and in accord with section 314.150(c) of the Federal Food, Drug, and Cosmetic Act, action will be taken to withdraw approval of the application. Appropriate notice will be given by publication in the Federal Register in accord with section 314.152.

This withdrawal will not prejudice any future filing of the application. You may request that the information in this application be considered in connection with any resubmission.

Sincerely yours,

10/11/88

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drug Evaluation and Research

500 Spring Garden Street P.O. Box 7929 Philadelphia Pennsylvania 19101

Smith Kline &French Laboratories

Regulatory Affairs
(215) 751-3868

August 24, 1988

Benzedrine® (amphetamine sulfate) Tablets
NDA 83-900
(Vol. 12, p. 69)

WITHDRAWN

Marvin Seife, M.D., Director
Division of Generic Drug Monographs
Center for Drugs and Biologics (HFN-530)
Document Control Room 17B-45
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Seife:

Please refer to our Abbreviated New Drug Application for Benzedrine® (amphetamine sulfate) Tablets ANDA 83-900.

Smith Kline &French Laboratories discontinued marketing of Benzedrine® Tablets in September 1982; the expiration date for the last lot of product manufactured was December 1987. In accordance 21 CFR §314.150(c) we are hereby requesting withdrawal of ANDA 83-900.

Since the situation described above also applies to NDA 17-071 for Benzedrine® Spansule Capsules, we are making a simultaneous request to the Division of Neuropharmacological Drug Products for withdrawal of that NDA as well.

Please call me at (215) 751-6545 if you have any questions about this matter.

Sincerely,

Raymond Ragland Jr

Raymond Ragland, Jr., Ph.D.
Director
Regulatory Affairs

RR/DS

0975r/10

069

SK&F